EASEE®

THE FIRST MINIMALLY INVASIVE BRAIN PULSE GENERATOR FOR FOCAL EPILEPSY IS ON THE MARKET

On the occasion of the publication in JAMA Neurology on April 4, 2023, we are informing you about the innovative brain pulse generator EASEE®.

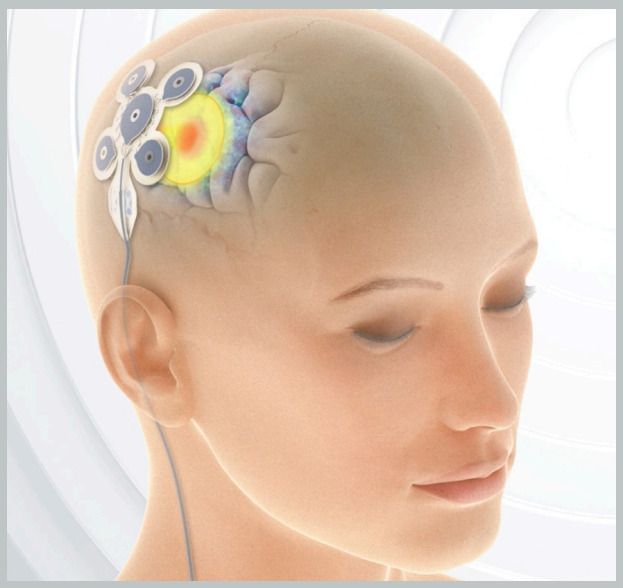
After some specialized epilepsy centers have already gained experience with EASEE® as part of the approval studies, we can now also keep colleagues in the private practice up to date on the possibilities of minimally invasive brain stimulation in patients with focal drug-refractory epilepsies.

Summary:

- **53% responder rate** after six months of active stimulation
- Convincing benefit-risk profile
- Register study for the evaluation of long-term effects is conducted by Prof. Schmitz in Berlin

OBJECTIVE

Two prospective non-randomized, single-arm trials included 33 adults to show if long-term treatment using epicranial electrical focal cortex stimulation with a novel implantable device (EASEE®) reduces seizure frequency in patients with drug-refractory focal epilepsy.



ENROLLMENT

Patients with drug-refractory focal epilepsy were recruited at **7 European epilepsy centers** from January 2019 to January 2020.

They were implanted with the EASEE® System and were evaluated after 6 months of active stimulation.

The treatment with EASEE® was an adjunctive treatment for adult patients with drug-refractory focal epilepsy.

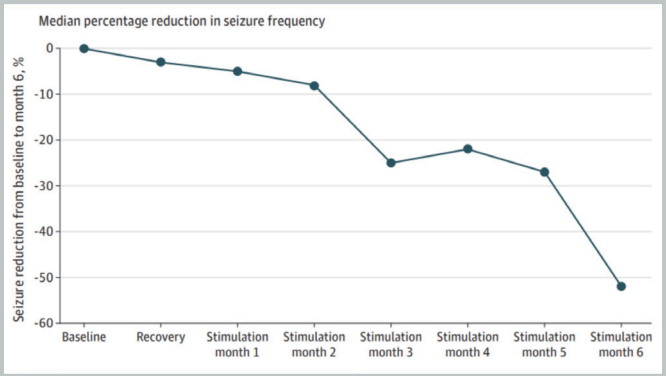
33 adult participants with uncontrolled focal epilepsy were implanted subcutaneously with a pulse generator and an electrode array placed above the individual focus region.

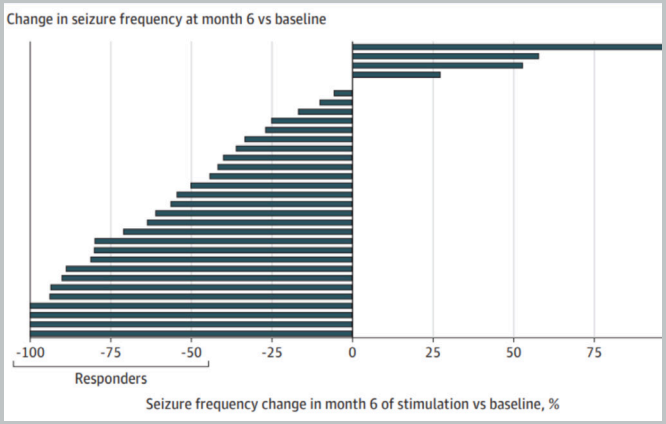
ENDPOINTS

Endpoints were defined as safety and efficacy measures.

The safety was analysed by the incidence of device or procedure related serious adverse events that occurred as of the implant procedure and up to the following 4 months.

The primary efficacy endpoint was the responder rate (defined as at least 50% reduction in seizure rate from baseline) after 6 months of active stimulation.





RESULTS

- The mean implantation procedure duration was 1:21 hours.
- **Safety: no device or procedure related serious adverse events** were reported in 33 patients.
- **Efficacy was shown with a responder rate of 53% at 6 months** in 32 out of 33 patients who received neurostimulation and were analyzed.

CONCLUSION

Results indicate that focal cortex stimulation with an epicranial electrode array can be a **safe and effective new treatment option** for patients with drug-refractory focal epilepsy.

JAMA Network™

Read here the detailed results →

https://jamanetwork.com/journals/jamaneurology/fullarticle/2802793

ARTICLE INFORMATION
Accepted for publication in JAMA Neurology: December 13, 2022.
Published Online: March 27, 2023. doi:10.1001/jamaneurol.2023.0066

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